REMARKS

Applicants respectfully request consideration of the foregoing amendments and the following commentary upon reexamination of the present application on the merits.

I. Introduction

Claim 4 has been cancelled without prejudice or disclaimer thereof. Claim 1 has been amended with support in the original specification, for example, at page 46, paragraph [0137]; and at page 50, paragraph [0142]. Claim 13 has been amended to delete the recitation of "a non-ionic surface stabilizer" and "an ionic surface stabilizer."

Because no new matter is introduced, Applicants respectfully request entry of this amendment. Upon entry, claims 1-3, 5-41 and 43-108 are pending, with claims 8, 15-16, 23-27 and 48-108 withdrawn from consideration.

II. Response to the Examiner's commentary in the Advisory Action

The prior art does not teach the expressly claimed surfactants in claim 14 or that the surface stabilizer is a surfactant.

Claim 14 recites specific surface stabilizers of the invention. This list does not include PLA. None of the secondary references cure this deficiency. Withdrawal of the rejection with respect to claim 14 is respectfully requested.

The Examiner emphasizes that the claimed invention is not distinguishable from the cited art because "applicant did not define a stabilizer as solely a surfactant" (Advisory Action, page 2, lines 20-21). The claims have been amended to recite that the surface stabilizer is a surfactant. Accordingly, withdrawal of the rejection with respect to claim 1 is respectfully requested.

Notwithstanding the above, the Applicants also offer the following comments in support of the patentability of the pending claims.

A. The two "embodiments" in Krause.

Throughout prosecution, the Examiner recognized that there are two embodiments disclosed in Krause. The first is where the triamcinolone particles are encapsulated in the center of a PLA sphere which PLA sphere has a diameter of less than 1 micron. Therefore, according to the Examiner, the particle size of the encapsulated triamcinolone has to be less than the particle size of PLA particles, i.e., less than 1 micron. The Examiner also asserts that encapsulation of the triamcinolone by the PLA reads on the claim limitation of a surface stabilizer adsorbed onto the surface of the triamcinolone particle.

The second embodiment of Krause describes that some of the triamcinolone particle may not be encapsulated, but located on the surface of the PLA sphere. The Examiner also asserts that this is a teaching of the claimed limitation of a surface stabilizer adsorbed on the surface of the triamcinolone particles.

B. Encapsulation is not necessarily adsorbed on the surface.

One of ordinary skilled in the art would not recognize the teaching of encapsulating a particle (such as described and illustrated in Krause) reads on the claim limitation of a surface stabilizer adsorbed on the surface of a particle.

"Encapsulate" is understood by one of ordinary skill in the art to mean enclose as if in a capsule or container. There is no necessary interaction between what is contained within the capsule or container other than that it is confined within. This is consistent with the descriptions and teachings of the PLA structure in Krause, for example, Fig. 2 and its description: "...Note highly porous interior structure" of the PLA nanoparticles as a drug carrier (*see* page 148 3rd par.). Also, Krause describes that the drug crystals embedded in the center of the spheres dissolve slower than the dissolution medium needs to invade the sphere through pores to dissolve the drug, and that a saturated drug solution exists in these channels. *See* Krause, page 152, last 7 lines. There is nothing in the description in Krause or what would be understood by one of

ordinary skill in the art from the term "encapsulate," that meets the claim element requiring a specific physical relationship between the surface stabilizer and the surface of the triamcinolone particle .

Moreover, Applicants submit herewith as Exhibit A, a declaration executed by Dr. H. William Bosch and made of record in copending application Serial No. 09/952,032. Dr. Bosch attested to the fact that the surface stabilizers in a nanoparticulate active agent composition, unlike a composition comprising an encapsulated drug, behave as permeable layers allowing free interaction of the environmental conditions with the active agent. *See* Bosch Declaration, sections 5 and 9. Such a physical relationship is clearly different from that described in Krause.

Accordingly, any conclusion drawn from Krause as to whether the interior surface of the PLA sphere is adsorbed to the surface of the triamcinolone particle contained within is not supported by the express teachings of Krause and is merely an improper conjecture by the Examiner.

C. The second embodiment of Krause lacks a teaching of particle size.

The second embodiment of Krause is argued by the Examiner to show that the PLA is on the surface of the triamcinolone particle. This embodiment, however, lacks a description as to the particle size of the triamcinolone. If the Examiner contends that the second embodiment of Krause, i.e., one where the triamcinolone particle is located on the surface of the PLA sphere (see page 151 of Krause), renders obvious the claimed limitation of a surface stabilizer adsorbed on the surface of the triamcinolone particle, there is nothing in the description of this second embodiment that indicates the size of the triamcinolone particle so adsorbed. In addition, there is nothing in this second embodiment that would provide a reason for one of ordinary skill in the art to believe that the structural relationship (triamcinolone particle on the outside surface of the PLA sphere) prevents the triamcinolone particle from aggregating with other triamcinolone particles, which is a function of the claimed surface stabilizer.

CONCLUSION

The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extension fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Jan 16 2009 By _____

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